

REMARKS**Rejections Under 35 U.S.C. § 103**

Claims 1-12, 17-24 and 29-35 stand rejected under 35 U.S.C. 103(a) as unpatentable over Chen in view of Christensen. Applicants respectfully disagree.

Claim 1 is directed to an edible film composition comprising at least one film forming agent, wherein the film forming agent comprises a low viscosity hydrolyzed vegetable gum.

Chen is directed to a dosage unit in the form of a flexible, non-tacky, dry conveniently packaged film. (p. 6, lines 24-26). When removed from a package and placed on a mucosal surface, the film becomes a coating that adheres to the mucosal surface and then disintegrates and dissolves. (p. 6, lines 23-24). The dosage unit is designed to deliver active agents such as therapeutic agents, nutritional supplements, and hygiene aids. (p. 10, line 22-23). The dosage unit includes a water-soluble hydrocolloid. (p. 3, line 31). Chen does not disclose the use of hydrolyzed vegetable gum.

Christensen is directed to a process for producing low viscosity hydrolysable carbohydrate gums. (p. 2, lines 36-37). It is mentioned that hydrophilic gums must be low in viscosity to be useful in film-forming applications or to be palatable in food applications. (p. 2, lines 32-35). Christensen does not mention the use of the gum in an edible film. Christensen also does not mention the use of flavoring agents with the gum, or the mouth texture of the gums. Therefore, Christenson does not provide any information on how suitable the hydrolysable carbohydrate gums would be in an edible film application.

Obviousness requires some suggestion or motivation to combine the references. There is no suggestion or motivation to combine Christensen with Chen. Although Christensen suggests that hydrophilic gums must be low in viscosity to be useful in film-forming applications or to be palatable in food applications, it does not mention that the disclosed hydrolysable carbohydrate gums are suitable for edible film applications. Additionally, Christensen does not

mention that the disclosed hydrolysable carbohydrate gums are suitable for use with flavorings, or that they would have a suitable mouth feel or texture for an edible film. The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680 (Fed. Cir. 1990).

Because Christensen does not disclose or suggest that the disclosed hydrolysable carbohydrate gums would be desirable to be used in an edible film, claim 1, and claims 2-12, 17-24 and 29-35 dependent thereon, are not obvious. Applicants respectfully request that the rejections be withdrawn.

In addition to the fact that there is no motivation to combine Chen and Christensen, the present invention yields unexpected results. Presence of an unexpected property is evidence of nonobviousness. (MPEP 716.02(a)). As described in the present application, previous edible films have disadvantages such as slow dissolution, gummy mouthfeel, and off-taste. (¶ [0001], lines 6-9). The claimed edible films have superior properties to the prior art hydrocolloid films disclosed in Chen. The present application lists experimental results comparing two films, a control including carrageenan (a hydrocolloid) and Example A, an inventive film including hydrolyzed guar gum. (Table 1). According to a descriptive panel who compared films made from the two formulations, Example A "was quicker to dissolve, not as gummy and had a deeper flavor note as compared to the Control." (¶ [0030]). There are several properties that are important to make an acceptable edible film, including processability, brittleness, dissolution, mouth feel, and taste. Changing the film forming agent in an edible film would be expected to change some or all of these important properties. Thus, it would not be expected that changing a film composition to a completely different type of film forming agent would result in an edible film with improved properties over the prior art films. Therefore, the claimed edible film using a hydrolyzed vegetable gum has improved and unexpected results compared to the prior art film using a hydrocolloid gum (e.g., carrageenan). Therefore, claims 1-12, 17-24 and 29-35 are not obvious. Applicants respectfully request that the rejections be withdrawn.

Claims 13-16 and 25-28 stand rejected under 35 U.S.C. 103(a) as unpatentable over Chen modified by Christensen and further in view of Leung. All of these claims are dependent on claim 1. In addition, claims 13-16 are directed to fillers, claims 25 and 26 are directed to cooling agents, and claims 27 and 28 are directed to heating agents. For the same reasons described above for claims 1-12, 17-24 and 29-35, there is no suggestion or motivation to combine Chen with Christensen. Additionally, there would be no motivation to combine Leung with Chen and Christensen. Leung is directed to oral film compositions. Although Leung discloses several film-forming agents, hydrolyzed vegetable gums are not disclosed or suggested. Leung discloses that "[a] major difficulty in formulating a film having such a relatively high oil content is that simply increasing the amount of oil in the film without determining the precise proportions of the many other ingredients typically results in a film that is too moist and therefore difficult to handle or process." (col. 4, lines 50-55). Thus, Leung acknowledges that the processing properties of the film greatly depend on the composition. There is no suggestion that the flavorings disclosed in Leung would work properly in a film composed of a different substance (i.e. hydrolyzed vegetable gum). Therefore, claims 13-16 and 25-28 are patentable over Leung, Chen, and Christensen.

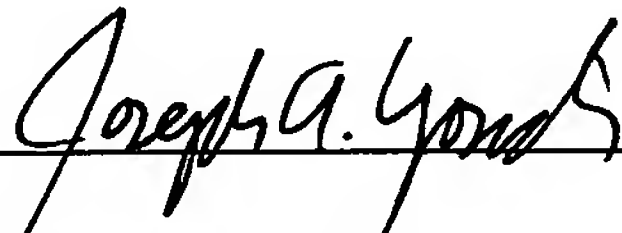
In addition to the fact that there is no motivation to combine Leung with Chen and Christensen, the present invention yields unexpected results. The claimed edible films have superior properties to the prior art hydrocolloid films disclosed in Chen, particularly mouth feel and flavor properties, as described above in the discussion for claims 1-12, 17-24 and 29-35. As discussed in both the present application and in Leung, changing the ingredients in an edible film would be expected to change the processability, brittleness, dissolution, mouth feel, and taste. Thus, it would not be expected that an edible film with a completely different type of film forming agent would result in an edible film with improved mouth feel and flavor properties over the prior art films. Therefore, the claimed edible film using a hydrolyzed vegetable gum has improved and unexpected results compared to the prior art film. Therefore, claims 13-16 and

25-28 are not obvious for these additional reasons. Applicants respectfully request that the rejections be withdrawn.

SUMMARY

Applicants believe the present application is in condition for allowance. If the Examiner has any remaining issues, she is invited to contact the undersigned attorneys for the Applicants via telephone if such communication would expedite this application.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Joseph A. Yosick", is written over a horizontal line.

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